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Dear Ms. Vela:

The Center for Environmental Health ("CEH") thanks the Office of Environmental Health Hazard and Assessment for the opportunity to comment on the proposed amendment to Article 8 of Title 27 of the California Code of Regulations, section 25821 ("Section 25821"). CEH offers the following comments.

1. Section 25821 and the accompanying Statement of Reasons should make clear that averaging of the "level in question" is not appropriate in all circumstances.

While averaging of the "level in question" of a chemical in food products may be appropriate in certain circumstances, Section 25821 should clarify that it is not appropriate in all circumstances. By way of example, if a cookie bakery produces a cookie Batch A using molasses of known high lead content and then manufactures a second Batch B with low lead molasses, averaging of Batch A and Batch B is not allowed and contrary to the statute. The exposures from Batch A require a warning under the statute as they are knowing and intentional exposures. The fact that Batch B may not require a warning does not allow for unwarned exposures to consumers who eat cookies from Batch A. Section 25821 should clarify that averaging of different units of a food product is only appropriate under certain facts and circumstances such as when a business knows that levels of some food products grown in a particular locale will require a warning but is not clear on which specific units exceed the warning threshold for a particular chemical.

2. Section 25821 should clarify that averaging of the "level in question" is not appropriate across products produced at different times.

Section 25821 should clarify that in cases where averaging may be appropriate, food products may only be averaged with other food products that were manufactured or produced on the same day or in the same production run. Without such a time restriction, businesses would be able to average food products grown, manufactured or produced over different lots, seasons and even years. For instance, if a business knows that food produced in a certain season contains chemicals at levels requiring a Proposition 65 warning, it would be contrary to the statute to allow such business to avoid warning simply because food products produced at a different time or in a different season did not contain chemicals at levels requiring a Proposition 65 warning. The Initial Statement of Reasons recognized this problem but declined to address it specifically. ISOR p. 5. This issue could be resolved by adding the words "produced or manufactured on different days, in different production runs" to the newly added sentence and adding a comma before the final clause of the section such that the additional language would read:

For purposes of this section, where a business presents evidence for the "level in question" of a listed chemical in a food product based on the average of multiple samples of that food, the level in question may not be calculated by averaging the concentration of the

chemical in food products produced or manufactured on different days or in different production runs, from different manufacturers or producers, or that were manufactured in different manufacturing facilities, from the product at issue.

3. Section 25821 should make clear that food products grown in disparate locations may not be averaged to determine a "level in question."

OEHHA's proposed amendment to Section 25821 makes clear that food products from different manufacturers may not be averaged together to determine the "level in question," but it fails to address the issue of averaging food products grown in different counties, states or even countries. Section 25821 should clarify that food products grown in a particular locale may not be averaged with food grown in a different locale. For instance, if a business knows that food grown in a particular locale contains chemicals at levels requiring a warning, it may not avoid a warning obligation because it grows the same food that does not contain those chemicals at levels requiring a warning in other counties, states or countries.

4. Section 25821 should clearly state that averaging is not appropriate for non-food products.

While averaging of multiple samples of a food product may be appropriate in certain circumstances to address the natural variability of chemical levels in such products, averaging is not appropriate in non-food products. Natural variability is less of an issue in non-food products where manufacturers control the ingredients and manufacturing process and know or should know the chemical content of parts and components as well as the finished products. The proposed amendment should clarify that averaging is not appropriate in non-food products.

5. Section 25821 should clarify that the level in question must allow for the fact that a particular product may have different average users.

Many products have significantly different users who are exposed to chemicals in those products at different levels. The fact that exposures to some product users may not require a warning should not alleviate a company's warning obligation to another group of distinct users who are exposed to chemicals at levels requiring a warning. For instance, average consumer users of nail polish may not be exposed to toluene in the nail polish at levels requiring a warning. However independent contractor cosmetologists who apply nail polish during a normal work day may be exposed to toluene at levels requiring a warning. Section 25821 should make clear that the average user must be considered in each distinct use scenario such that the independent contractor cosmetologists are not deprived of a warning simply because the consumer exposures do not require one.

6. OEHHA should likewise clarify that the arithmetic mean is to be used to determine the rate of intake or exposure to carcinogens in consumer products.

The proposed amendment is limited to section 25821(c), which addresses assumptions to be used in calculating the reasonably anticipated rate of exposure to chemicals listed as reproductive toxicants under Proposition 65. However, there is no reason to treat carcinogens any differently for this purpose. Therefore, the same

amendment should be made to the corresponding regulation governing the calculation of exposures to carcinogens in consumer products. *See* 27 Cal. Code Regs. § 25721(d)(4).

7. The amendment to Section 25821(c)(2) should apply only to data used to calculate the "rate of intake or exposure" and not be used to determine which members of the public receive warnings.

Defendants in Proposition 65 cases have been applying the geometric mean to data such as the NHANES surveys conducted by the United States Department of Agriculture for some time. The geometric mean, which is often a level of magnitude less than the arithmetic mean, is then used to calculate the appropriate serving sizes for use in determining the "level of exposure" in Proposition 65 cases. The proposed amendment to Section 25821 addresses this problem and specifies that the use of the geometric mean is not appropriate and that the arithmetic mean must be used. This is the correct interpretation and CEH applauds OEHHA for this.

However the amendment should make clear that the arithmetic mean is appropriate only when applied to such data and for the purpose of determining information like the appropriate serving size and not for determining which individuals receive warnings. This is particularly true because Health and Safety Code Section 25249.6 states that "No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning…" The statute thus refers to "any individual" and does not restrict which exposed individuals receive warnings. Courts have interpreted this to mean the 75th to 85th percentile and the OEHHA Final Statement of Reasons repeatedly mentions the 95th percent confidence limits in discussing appropriate standards for Proposition 65 toxicology. *See DiPirro v. Bondo*, 153 Cal.App.4th 150, 194 (2007) and OEHHA Final Statement of Reasons: Article 7. To address this issue, Section 25821 should clarify that the arithmetic mean is appropriate only when limited to data such as that produced by the United States Department of Agriculture used to calculate the level in question. The language of Section 25821 would then read:

(2) For exposures to consumer products, the level of exposure shall be calculated using the reasonably anticipated rate of intake or exposure for average users of the consumer product, and not on a per capita basis for the general population. ~~This rate of intake or exposure is calculated as the arithmetic mean of the rate of intake or exposure for users of the product.~~ The rate of intake or exposure shall be based on data for use of a general category or categories of consumer products, such as the United States Department of Agriculture Home Economic Research Report, Foods Commonly Eaten by Individuals: Amount Per Day and Per Eating Occasion, where such data are available. When using such data, the rate of intake or exposure is calculated as the arithmetic mean of the rate of intake or exposure for users of the product.

Conclusion

CEH appreciates OEHHA's effort to clarify and improve Section 25821. Addressing each of the preceding comments will enhance these improvements by reducing ambiguity

and ensuring that individuals in California are provided with clear and reasonable warnings prior to exposure to toxic chemicals.

Sincerely,

Caroline Cox
Research Director